

REMARKS

Claims 1-2, 6-13, 17-29, 32-57, and new claims 58-59, are pending for the Examiner's review and consideration. Claims 3-5 and 14-16 are cancelled herein without prejudice to Applicants' rights to file one or more continuing applications directed to this or other unclaimed subject matter. Claims 5-7 and 16-18 were rewritten in independent form, with claims 1 and 12 reciting the features of independent, rewritten claims 5 and 16.

Applicants note for the record that the peptide Ac—D—Nal—D—Cpa—D—Pal—Ser—Tyr—D—Hci—Leu—Ilys—Pro—D—Ala—NH₂ recited in the claims is commercially available under the tradename Teverelix®. Claim 8 was amended to change the claim's dependency. Claim 29 was amended to depend from claim 12. New claims 58-59 recite specifically preferred counter-ions for use in the present invention. These counter-ions are also recited in claims 2 and 13. No new matter has been added by way of these amendments and new claims, such that their entry at this time is warranted.

The Office Action indicates that claims 5-8 and 16-19 would be allowable if rewritten in independent form to include all of the limitations of the base claim and any intervening claims (page 5). As discussed above, Applicants have amended the claims to make these necessary changes.

The Office Action further states that claims 32-57 are directed to an invention that is independent or distinct from the invention originally claimed (page 2). In particular, the Office Action maintains that the original independent claims are broad generic claims while claims 32-57 are directed to species of invention (*Id.*). Applicants respectfully traverse.

The subject matter of claims 32-57 is not directed to a different invention from that originally claimed. Both independent claims 32 and 45 claim a suspension of a salt of the peptide that was specifically recited in claim 5, with a counter-ion that was specifically recited in claim 2. These features were present in the claims as originally filed. Indeed, these features now form the allowed claim 1. Claims 41-44 and 54-57 are directed to methods of preparing a lyophilized composition, lyophilized compositions, and methods of preparing a suspension from a lyophilized composition. These features were present in originally filed claims 26-29. Accordingly, Applicants submit that no serious burden is placed on the Examiner by the examination and allowance of claims 32-57 with the other pending claims.

In addition, this subject matter was pending before the Examiner at the time of the issuance of the first Office Action. With all due respect, it is noted that the Patent Office

requires Examiners to make a proper restriction requirement as early as possible in the prosecution, and in the first action if possible. *See* MPEP § 811. Before making a restriction requirement after the first action on the merits, the Examiner is instructed to consider whether there will be a serious burden if restriction is not required. *Id.* Imposition of a restriction at this late a stage of the prosecution places an undue burden on the Applicants. Indeed, restriction now will require the ultimate burden if maintained—the need for filing a separate patent application to pursue subject matter claimed in the originally filed application that is part of the same invention pending in this application. Therefore, Applicants respectfully request that the Examiner reconsider and withdraw the restriction requirement, and examine claims 32-57 along with the other claims of the recited invention.

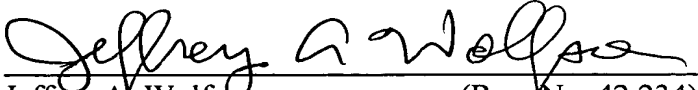
Claims 1-4, 9-15, and 20-29 were rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. The Office Action asserts that the use of the broad term "peptide or peptidomimetic" in the claims is not supported by the disclosure. This language is well known to those of ordinary skill in the art, particularly with reference to the present application. To expedite prosecution, however, claims 1 and 12 have been amended to include the specific structure of a preferred peptide, Ac—D—Nal—D—Cpa—D—Pal—Ser—Tyr—D—Hci—Leu—Ilys—Pro—D—Ala—NH₂, which is clearly supported in the Specification. Claims 2 and 9-11 depend from claim 1. Claims 13 and 20-29 depend from claim 12. Accordingly, as these claims now refer to a specific peptide, it is believed that this rejection has been overcome and should be reconsidered and withdrawn.

Applicants now believe all claims to be in condition for entry and allowance. Should the Examiner not agree with this position, a telephone or personal interview is requested to resolve any remaining issues and expedite allowance of this application.

Respectfully submitted,

11/19/04

Date



Jeffrey A. Wolfson (Reg. No. 42,234)

WINSTON & STRAWN LLP
Customer Number: 28765

202-371-5770